

**BEFORE THE
MISSOURI BOARD OF PHARMACY
STATE OF MISSOURI**

IN RE:

QUALGEN, LLC
14844 Bristol Park Blvd. Edmond, OK 73013
Permit Number: 2015029209

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Case #2019-000984

**ORDER OF THE MISSOURI BOARD OF PHARMACY
ISSUING QUALGEN, LLC
A DRUG OUTSOURCER LICENSE SUBJECT TO PROBATION**

Comes now the Missouri Board of Pharmacy ("Board") and issues its ORDER granting a PROBATED drug outsourcer license, license number 2015029209, to QUALGEN, LLC ("QUALGEN") pursuant to the provisions of Section 324.038, RSMo. As set forth in Section 324.038, RSMo, QUALGEN, LLC may submit a written request for a hearing to the Administrative Hearing Commission seeking review of the Board's decision to issue a probated license to QUALGEN, LLC. Such written request must be submitted to the Administrative Hearing Commission within thirty (30) days of issuance of this Order. The written request should be addressed to the Administrative Hearing Commission, P.O. Box 1557, Truman Building Room 640, Jefferson City, MO 65102-1557. If no written request for review is received by the Administrative Hearing Commission within the thirty (30) day period, the right to seek review of the Board's decision shall be waived.

The disciplinary period shall become effective immediately upon issuance of QUALGEN, LLC's drug outsourcer license. Should QUALGEN, LLC file a written request for review of this Order, the terms and conditions of the Order shall remain in force and effect unless and/or until such time as the Administrative Hearing Commission issues an order contrary to this Order.

FINDINGS OF FACT

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo, for the purpose of executing and enforcing provisions of Chapter 338, RSMo.
2. QUALGEN filed an application for a drug outsourcer license with the Board on March 1, 2019, to convert its drug distributor permit to a drug outsourcer license. The license issued pursuant to this Order is in response to that application.

3. On August 23, 2017, Qualgen entered into a settlement agreement with the Board for a probated drug distributor permit based upon discipline Qualgen had received in Oklahoma. The Board incorporates that settlement agreement of August 23, 2017. The Board assigned QUALGEN, LLC a drug distributor permit, numbered 2015029209, subject to the terms of probation as set forth in that settlement agreement.

4. That settlement agreement is incorporated by reference.

5. Qualgen, LLC 14844 Bristol Park Blvd., Edmond, Oklahoma is permitted by the Board as a drug distributor, permit number 2015029209. Qualgen's permit was at all times relevant herein current and active.

6. On or about June 15, 2016, Qualgen and the Oklahoma Board of Pharmacy ("Oklahoma Board") executed Agreed Findings of Fact, Conclusions of Law and Final Order (the "Oklahoma Order") after the Oklahoma Board filed a Complaint against Qualgen. The Complaint and Oklahoma Order are incorporated herein.

7. In the Oklahoma Order, Qualgen admitted guilt as to certain Counts in the Complaint. Qualgen was placed on probation for five (5) years until June 15, 2021 and was fined \$100,000.00.

8. This Order is issued in response to the application filed on August 23, 2017.

9. Based on information received by the Board, pursuant to Section 338.055 RSMo, the Board concluded QUALGEN, LLC engaged in conduct which would be grounds for denying QUALGEN, LLC a license as a drug outsourcer, or if it had been currently licensed by the Board as a drug outsourcer, disciplinary action by the Board against its drug outsourcer license.

10. Pursuant to the provisions of Section 324.038, RSMo, the Board hereby issues drug outsourcer license number 2015029209 to QUALGEN, LLC in lieu of denial of QUALGEN, LLC's request for a license to act as a drug outsourcer in Missouri. Permit number 2015029209 is issued subject to the terms and conditions set forth herein below.

CONCLUSIONS OF LAW

11. QUALGEN, LLC's conduct as alleged above is cause for the Board to deny QUALGEN, LLC a permit to practice pharmacy pursuant to Section 338.055.1 and .2, RSMo, which states in pertinent parts:

1. The board may refuse to issue any certificate of registration or authority, permit or license required pursuant to this chapter for one or any combination of causes stated in subsection 2 of this section or if the designated pharmacist-in-charge,

manager-in-charge, or any officer, owner, manager, or controlling shareholder of the applicant has committed any act or practice in subsection 2 of this section.

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

(8) Denial of licensure to an applicant or disciplinary action against an applicant or the holder of a license or other right to practice any profession regulated by this chapter granted by another state, territory, federal agency, or country whether or not voluntarily agreed to by the licensee or applicant, include, but not limited to, surrender of the license upon grounds for which denial or discipline is authorized in this state;

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government.

12. Section 324.038.1, RSMo, provides in pertinent part:

1. Whenever a board within or assigned to the division of professional registration, including the division itself when so empowered, may refuse to issue a license for reasons which also serve as a basis for filing a complaint with the administrative hearing commission seeking disciplinary action against a holder of a license, the board, as an alternative to refusing to issue a license, may, at its discretion, issue to an applicant a license subject to probation.

13. The Board hereby issues this ORDER in lieu of denial of QUALGEN, LLC's request for a license to provide drug outsourcer services in Missouri pursuant to Section 324.038, RSMo.

ORDER

14. Based on the foregoing, it is the ORDER of the Missouri Board of Pharmacy that, in lieu of denying a drug outsourcer, the Board hereby issues Qualgen, LLC a drug outsourcer license

number 2015029209 subject to **PROBATION** for the same period of time its drug distributor permit is under discipline ("disciplinary period") and will terminate on 09/06/2022 if Qualgen complies with all the terms of this Order. This Order shall become effective on the date of this Order. The terms of discipline shall be identical to those entered in the August 23, 2017 settlement agreement. Those terms are set forth below:

A. Qualgen shall pay all required fees for licensing to the Board and shall renew its drug distributor license prior to October 31 of each licensing year.

B. Qualgen shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

C. If requested, Qualgen shall provide the Board a list of all licensed pharmacists employed by the Qualgen, and the individuals' current home addresses and telephone numbers.

D. If, after disciplinary sanctions have been imposed, Qualgen fails to keep its drug distributor license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

E. Qualgen shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of its disciplinary order.

F. Qualgen shall not serve as an intern training facility for Missouri interns.

G. Qualgen shall make a representative of the drug distributor available for personal interviews to be conducted by a member of the Board or the

Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Qualgen will be notified and given sufficient time to arrange these meetings.

H. Qualgen's failure to comply with any condition of discipline set forth herein constitutes a violation of this Order.

I. The parties to this Order understand that the Board of Pharmacy will maintain this Order as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

15. Upon the expiration of said discipline, Qualgen's license as a drug outsourcer in Missouri shall be fully restored if all other requirements of law have been satisfied provided, however, that in the event the Board determines that the Qualgen has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline Qualgen.

16. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.


17. If the Board determines that Qualgen has violated a term or condition of this Order, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Order in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Order occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a

violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Order has occurred.

18. The Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

SO ORDERED this 13th day of June, 2019

BOARD SEAL



KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR
MISSOURI BOARD OF PHARMACY